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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
087704,159	08/28/96	WILLIAMS	OPHD-02304

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EXAMINER
NAVARRO, A

ART UNIT	PAPER NUMBER
1645	19

DATE MAILED: 12/03/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/704,159**

Applicant(s)

**Williams et al**

Examiner  
**Mark Navarro**

Group Art Unit  
**1645**



☒ Responsive to communication(s) filed on Sep 13, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 10-14 and 25-31 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 10-14 and 25-31 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Application/Control Number: 08/704,159

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### DETAILED ACTION

Applicant's amendment filed September 13, 1999 (Paper Number 18) has been received and entered. New claims 29-31 have been added, consequently claims 10-14 and 25-31 are pending in the instant application.

#### *Claim Rejections - 35 USC § 103*

1. The rejection of claims 10-14 and 25-28 under 35 U.S.C. 103(a) as being unpatentable over Thompson *et al* (Eur. J. Biochem. 189: 73-81 (April 1990)) in view of Binz *et al* (J. Biol. Chem. 265: 9153-9158 (June 1990)), Roitt (Essential Immunology, Sixth Edition, Blackwell Scientific Publications, Boston, MA, pp 173-178 (1988)), LeClerc *et al* (J. Immunol. 144(8): 3174-3182 (Apr 1990)), Kleid (Annals NY Acad. Sci. 413: 23-30 (1983)), and Siegel (J. Clin. Microbiol. 26: 2351-2356 (Nov 1988)), is withdrawn.

#### *Claim Rejections - 35 USC § 112*

2. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "substantially" endotoxin-free is withdrawn in view of Applicant's arguments.

The following new grounds of rejection are applied to the claims:

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***Claim Rejections - 35 USC § 112***

3. Claims 10-14 and 25-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a soluble and neutralizing vaccine comprising a fusion protein, said fusion protein comprising a non-toxic protein sequence and at least a portion of one or more *Clostridium botulinum* toxins, said one or more toxins selected from the group consisting of type B toxin and type E toxin.

The specification provides insufficient guidance of how to use the claimed portions as a soluble and neutralizing vaccine. It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A *et al.*, (ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen." One of skill in the art would be forced into undue experimentation to identify all portions of a single antigen which can be produced as a soluble and neutralizing vaccine, given that the art teaches of the unpredictability of using a single

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antigen for vaccination it would be an undue burden and be unpredictable to use the broadly claimed soluble and neutralizing vaccine portions for vaccination.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Dr. Anthony Caputa can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Patent Examiner

December 2, 1999